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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/631,637	08/02/2000	Jean Gosselin	2097/49123	8660

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CROWELL & MORING, LLP  
INTELLECTUAL PROPERTY GROUP  
P. O. BOX 14300  
WASHINGTON, DC 20044-4300

EXAMINER

WINKLER, ULRIKE

ART UNIT	PAPER NUMBER
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1648

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DATE MAILED: 03/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action**

Application No.

09/631,637

Applicant(s)

GOSSELIN ET AL.

Examiner

Ulrike Winkler, Ph.D.

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--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 13 February 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY [check either a) or b)]**

- a) ☒ The period for reply expires 6 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on 13 February 2003. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see Note below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_

3. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: see attached.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: \_\_\_\_\_.

Claim(s) objected to: \_\_\_\_\_.

Claim(s) rejected: 1-3, 5-10.

Claim(s) withdrawn from consideration: \_\_\_\_\_.

8. ☐ The proposed drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_.
10. ☐ Other: \_\_\_\_\_

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Applicant traverses the restriction among the linked inventions on the grounds that the office has failed to show “independent and distinct” invention which pose a “serious burden” on the examiner. The compounds in question are structurally different and would require searching in different class and subclass: AZT (514/50), 3TC (514/49) and bpV (424/646) indicating that the search would cover divergent subject matter which by definition would make it a burdensome search. Therefore, Applicant’s arguments regarding the restriction requirement are not convincing.

The rejection of claims 1-3 6-10, 16-19 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention **is maintained** for reasons of record.

Applicant’s arguments are that the Barbeau et al. (Journal of Biological Chemistry, 1997) cited in the prior rejection is not in conflict with the instantly claimed invention because the reference utilizes latently infected T-cells and there is no indication of “viral particle release”. Applicant arguments are that the experiments in the Barbeau et al. reference are directed to the early life cycle events while the instant invention assays late cycle events. Applicant’s arguments have been fully considered but they fail to persuade the office for the following reasons. Barbeau et al. clearly state in the abstract “Finally we tested the PTP inhibitors in four cell lines latently infected with HIV-1 and showed a consistent pV-mediated increase in virion production”. Upon close scrutiny of the cited art the luciferase assay or CAT assays in the reference actually measures particle release from the latently infected cells (see page 12969, column 2, lines 44-59). In other words the observation that pV-mediated an increase in the particle release indicates that the same viral life cycle event is measured. Briefly the assay takes cell-free supernatant from the plates and adds lysis buffer, this is to disrupt the viral particle and release the enzyme from within the viral particle, the enzyme activity is assayed after adding the appropriate substrate. Therefore, the reference remains in direct conflict with the instantly claimed invention.

Applicant has cited that MPEP §2164.02 as indicating that *in vitro* data could be used to correlate *in vivo* activity. However, in the case of HIV this extrapolation of *in vitro* data to in

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*in vivo* applicability is clearly not predicable as evidenced by Sandström et al. and Mitsuya et al. (cited in the prior office action). Here suramin worked well in *in vitro* assays but when applied to *in vivo* treatment the concentration of compound could not be administered at does high enough to provide a treatment because these concentrations are toxic. The bar is raised even higher in the in conjunction with the observation by Barbeau et al. that pV increases viral particle release in direct opposition of what is being claimed in the instant invention that the pV is an inhibitor of a viral infection (HIV). Thus, the lack of working examples regarding treatment of any retroviral infection including HIV in a patient, the lack of guidance in the specification, and the unpredictability regarding extrapolating *in vitro* data to an *in vivo* treatment method greatly reduces the probability that one of skill in the art would successfully obtain the claimed invention without undue experimentation. Therefore, the instant rejection is maintained.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ulrike Winkler, Ph.D. whose telephone number is 703-308-8294. The examiner can normally be reached M-F, 8:30 am - 5 pm. The examiner can also be reached via email [ulrike.winkler@uspto.gov].


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached at 703-308-4027.

The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 or for informal communications use 703-746-3162.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



Ulrike Winkler, Ph.D.



JAMES HOUSEL 3/23/03  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600